

General

Guideline Title

ACR Appropriateness Criteria® liver lesion — initial characterization.

Bibliographic Source(s)

Nelson RC, Kamel IR, Baker ME, Al-Refaie WB, Cash BD, Harrison SA, Hindman NM, Kaur H, McNamara MM, Qayyum A, Tulchinsky M, Yarmish GM, Rosen MP, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® liver lesion -- initial characterization [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 24 p. [81 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Lalani T, Rosen MP, Blake MA, Baker ME, Cash BD, Fidler JL, Greene FL, Katz DS, Miller FH, Small WC, Sudakoff GS, Yee J, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® liver lesion -- initial characterization. [online publication]. Reston (VA): American College of Radiology (ACR); 2010. 8 p. [36 references]

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Liver Lesion - Initial Characterization

<u>Variant 1</u>: Indeterminate >1 cm lesion on initial imaging with ultrasound or CT (without or with contrast) or non-contrast-enhanced MRI. Normal liver. (No suspicion or evidence of extrahepatic malignancy or underlying or liver disease.)

Radiologic Procedure	Rating	Comments	RRL*
Lesion Initially Identified on US			
MRI abdomen without and with contrast	8	MRI is best test for characterizing liver lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	O
MRI abdomen without contrast	6	Consider this procedure if MRI with gadolinium is contraindicated.	O

Radioden myithout and with contrast	7 Rating	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	RRL*
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to MRI and CT contrast agents.	
CT abdomen with contrast	7	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	
Lesion Initially Identified on CT			
MRI abdomen without and with contrast	8	Consider this procedure if CT characterization is incomplete. See statement regarding contrast in the text below under "Anticipated Exceptions."	0
MRI abdomen without contrast	7	Consider this procedure if MRI with gadolinium is contraindicated. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT.	O
US abdomen	5	Consider this procedure to diagnose a cyst versus solid lesion and to guide a percutaneous biopsy.	O
Lesion Initially Identified on MRI Without	t Contrast		
MRI abdomen without and with contrast	8	Consider this procedure to differentiate between benign and malignant lesion. See statement regarding contrast in the text below under "Anticipated Exceptions."	O
CT abdomen without and with contrast	7	Consider this procedure if MRI with gadolinium is contraindicated.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to CT and MRI contrast agents.	
CT abdomen with contrast	6	Consider this procedure if there is a contraindication to MRI contrast agents.	
US abdomen	5	This procedure is usually not indicated after MRI.	O
Lesion Initially Identified on US, CT, or N	MRI		
Percutaneous image-guided biopsy liver	5	Consider this procedure if imaging findings are atypical, inconclusive, or suspicious for malignancy after doing contrast-enhanced CT or MRI.	Varies
Tc-99m sulfur colloid scan liver	3	Consider this procedure to evaluate for FNH if GFR precludes CT or MRI contrast agents.	
Rating is trained liverally not appropria	te; 3,5,6 May be appropriate;	7.860 Sidenthiappropriate if a hemangioma is suspected	*Relative

Radiologic Procedure	Rating	and if GFR precludes CT or MRI contrast agents.	RRL*
In-111 somatostatin receptor scintigraphy	3	This procedure is not appropriate unless there is a known or suspected neuroendocrine tumor.	
FDG-PET/CT whole body	3	This procedure is not appropriate unless there is a known malignancy.	
Rating Scale: 1,2,3 Usually not appropriate	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 2</u>: Indeterminate >1 cm lesion on initial imaging with ultrasound, CT (without or with contrast), or non-contrast-enhanced MRI. Known history of an extrahepatic malignancy.

Radiologic Procedure	Rating	Comments	RRL*
Lesion Initially Identified on US			
MRI abdomen without and with contrast	8	Consider this procedure if the lesion is not cystic on US. See statement regarding contrast in the text below under "Anticipated Exceptions."	О
MRI abdomen without contrast	7	Consider this procedure if there is a contraindication to CT and MRI contrast agents.	О
CT abdomen without and with contrast	7	Consider this procedure if the lesion is not cystic on US.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to MRI and CT contrast agents. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT.	
CT abdomen with contrast	7	Consider this procedure if there is a contraindication to MRI.	
Lesion Initially Identified on CT			
MRI abdomen without and with contrast	8	Consider this procedure if CT characterization is incomplete. See statement regarding contrast in the text below under "Anticipated Exceptions."	О
MRI abdomen without contrast	6	A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT.	О
US abdomen	5	Consider this procedure if CT was performed without contrast and MRI is contraindicated.	О
Lesion Initially Identified on MRI Without	Contrast	!	!
Rating Scale: 1.2.3 Usually not appropria	te: 4 5 6 May be an	nronriate: 7 8 9 Usually appropriate	*Relativ

ARI abdemen without and with contrast	Rating	Consider this procedure to differentiate between benign and malignant lesion. See statement regarding	RRL*
		contrast in the text below under "Anticipated	
		Exceptions."	
CT abdomen without and with contrast	7	Consider this procedure if MRI with gadolinium is contraindicated.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to MRI and CT contrast agents. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT.	
CT abdomen with contrast	7	Consider this procedure if there is a contraindication to MRI contrast agents.	
US abdomen	5	Consider this procedure to differentiate between a cystic versus solid lesion or to guide a biopsy/intervention.	O
Lesion Initially Identified on US, CT, or N	MRI		
Percutaneous image-guided biopsy liver	7	Consider this procedure for obtaining a tissue diagnosis and when imaging is not conclusive.	Varies
FDG-PET/CT whole body	6	This procedure may be appropriate for complete staging based on size and avidity of the primary extrahepatic malignancy.	
Tc-99m sulfur colloid scan liver	3	Consider this procedure to evaluate for FNH if GFR precludes CT or MRI contrast agents.	
Tc-99m RBC scan liver	3	Consider this procedure if a hemangioma is suspected and if GFR precludes CT or MRI contrast agents.	
In-111 somatostatin receptor scintigraphy	3	Consider this procedure if the primary lesion is a neuroendocrine tumor and/or when symptoms or laboratory values indicate neuroendocrine malignancy.	
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate	e; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 3</u>: Indeterminate >1 cm lesion on initial imaging with ultrasound, CT (without or with contrast), or non-contrast-enhanced MRI. Known or suspected liver disease associated with a high risk of hepatocellular carcinoma (chronic hepatitis, cirrhosis, hemochromatosis, etc.)

Radiologic Procedure	Rating	Comments	RRL*	
Lesion Initially Identified on US				
Raning Schale in, 2, ith bist all with appropriate	e;,4,5,6 May be appropriate;	7, Bus Issinally expression in the structure of hepatitis B or C.	CRelative Padiation	

contrast Radiologic Procedure	Rating	See statement regarding contrast in the text below under "Anticipated Exceptions."	RRL*
MRI abdomen without contrast	6	Consider this procedure if there is a contraindication to CT and MRI contrast agents.	О
CT abdomen without and with contrast	7	This procedure is an alternative to MRI when GFR precludes gadolinium	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to MRI and CT contrast agents. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT.	
CT abdomen with contrast	6	Consider this procedure if there is a contraindication to MRI or MRI contrast agents.	
Lesion Initially Identified on CT			ı
MRI abdomen without and with contrast	9	Consider this procedure if CT is not conclusive and in scenarios where there has been prior intervention (i.e., radiofrequency/ablation, chemoembolization). See statement regarding contrast in the text below under "Anticipated Exceptions."	0
MRI abdomen without contrast	6	Consider this procedure if CT is not conclusive and there is a contraindication to gadolinium.	О
US abdomen	5	Consider this procedure to differentiate between a cystic versus solid lesion or to guide a biopsy/intervention.	О
Lesion Initially Identified on MRI Without	Contrast		
MRI abdomen without and with contrast	9	See statement regarding contrast in the text below under "Anticipated Exceptions."	О
CT abdomen without and with contrast	7	Consider this procedure as an alternative to MRI when GFR precludes use of gadolinium.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to MRI and CT contrast agents. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT.	
CT abdomen with contrast	6	Consider this procedure as an alternative to MRI when GFR precludes use of gadolinium.	
US abdomen	5	Consider this procedure to confirm a cystic lesion.	О
Lesion Initially Identified on US, CT, or M	ИRI		
Percutaneous image-guided biopsy liver	6	This procedure is useful if alpha-fetoprotein is low or features are not typical.	Varies
Rating Scalar Collo descally linest appropria	te; 34,5,6 May be appropriate;	71884 Lisuady appropriate irrhotic patients.	*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
Tc-99m RBC scan liver	3	A hemangioma is not common in patients with cirrhosis.	
In-111 somatostatin receptor scintigraphy	2	This procedure is not relevant to the detection or characterization of HCC.	
FDG-PET/CT whole body	2	This procedure is not useful for HCC staging.	
Rating Scale: 1,2,3 Usually not appropri	ate; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 4</u>: Indeterminate <1 cm lesion on initial imaging with ultrasound or CT (without or with contrast) or non-contrast-enhanced MRI. Normal liver. (No suspicion or evidence of extrahepatic malignancy or underlying liver disease.)

Rating	Comments	RRL*
8	See statement regarding contrast in the text below under "Anticipated Exceptions."	О
6	Consider this procedure if MRI with gadolinium is contraindicated	0
7	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	
3	Consider this procedure if there is a contraindication to MRI and CT contrast agents.	
6	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	
		I
8	Consider this procedure if characterization by CT is incomplete. See statement regarding contrast in the text below under "Anticipated Exceptions."	О
6	Consider this procedure if MRI with gadolinium is contraindicated. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT. However, this may not be the case for small lesions.	О
	8 6 7 3 6 8 8	See statement regarding contrast in the text below under "Anticipated Exceptions." Consider this procedure if MRI with gadolinium is contraindicated Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated. Consider this procedure if there is a contraindication to MRI and CT contrast agents. Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated. Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated. Consider this procedure if characterization by CT is incomplete. See statement regarding contrast in the text below under "Anticipated Exceptions." Consider this procedure if MRI with gadolinium is contraindicated. A noncontrast-enhanced MRI is superior to a noncontrast-enhanced CT. However, this

RSdfbldgte Procedure	Rating	Consider this procedure to differentiate between a cystic versus solid lesion or to guide a	RRL*
		biopsy/intervention.	
Lesion Initially Identified on MRI Without	Contrast		
MRI abdomen without and with contrast	8	Consider this procedure to differentiate between benign and malignant lesion. However, there may be challenges when attempting to characterize small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	О
CT abdomen without and with contrast	7	Consider this procedure if MRI with gadolinium is contraindicated.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to CT and MRI contrast agents.	
CT abdomen with contrast	6	Consider this procedure if there is a contraindication to MRI contrast agents.	
US abdomen	5	This procedure is usually not indicated after MRI.	О
Lesion Initially Identified on US, CT, or N	⁄IRI		I
Percutaneous image-guided biopsy liver	3	Consider this procedure if imaging findings are atypical, inconclusive, or suspicious for malignancy after performing CT or MRI with contrast. However, there may be challenges when attempting to biopsy small lesions.	Varies
Tc-99m sulfur colloid scan liver	3	Consider this procedure to evaluate for FNH if GFR precludes CT or MRI with contrast.	
Tc-99m RBC scan liver	3	Consider this procedure if a hemangioma is suspected and if GFR precludes CT or MRI with contrast.	
In-111 somatostatin receptor scintigraphy	2	This procedure is not appropriate unless there is a known or suspected neuroendocrine tumor.	
FDG-PET/CT whole body	3	This procedure is not appropriate unless there is a known malignancy.	
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate	e; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 5</u>: Indeterminate <1 cm lesion on initial imaging with ultrasound, CT (without or with contrast), or non-contrast-enhanced MRI. Known history of an extrahepatic malignancy.

Radiologic Procedure	Rating	Comments	RRL*
Lesion Initially Identified on US			
MRI abdomen without and with contrast	8	Although MRI is the best test for characterizing liver lesions, it may have limitations for characterizing small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	О
MRI abdomen without contrast	6	Consider this procedure if MRI with gadolinium is contraindicated	О
CT abdomen without and with contrast	7	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to MRI and CT contrast agents.	
CT abdomen with contrast	7	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	
Lesion Initially Identified on CT			
MRI abdomen without and with contrast	8	Consider this procedure if characterization by CT is incomplete, recognizing the limitations of MRI for characterizing small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	0
MRI abdomen without contrast	6	Consider this procedure if MRI with gadolinium is contraindicated.	О
US abdomen	5	Consider this procedure to differentiate between a cystic versus solid lesion or to guide a biopsy/intervention.	О
Lesion Initially Identified on MRI Without	t Contrast		
MRI abdomen without and with contrast	8	Consider this procedure to differentiate between benign and malignant lesion. However, there may be challenges when attempting to characterize small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	0
CT abdomen without and with contrast	7	Consider this procedure if MRI with gadolinium is contraindicated.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to CT and MRI contrast agents.	
Rating Scale: 1.2.3 Usually not appropria	te: 4.5.6 May be appropriate	: 7.8.9 Usually appropriate	*Relative

Ranbidgiorn with contrast	Rating	Consider this procedure if there is a contraindication to MRI contrast agents.	RRL*
US abdomen	4	This procedure is usually not indicated after MRI.	0
Lesion Initially Identified on US, CT, or M	ИRI		
Percutaneous image-guided biopsy liver	6	Consider this procedure if imaging findings are atypical, inconclusive, or suspicious for malignancy after performing a CT or MRI with contrast. However, there may be challenges when attempting to biopsy small lesions.	Varies
Tc-99m sulfur colloid scan liver	3	Consider this procedure to evaluate for FNH if GFR precludes CT or MRI with contrast.	
Tc-99m RBC scan liver	3	Consider this procedure if a hemangioma is suspected and if GFR precludes CT or MRI with contrast.	
In-111 somatostatin receptor scintigraphy	3	This procedure is not appropriate unless there is a known or suspected neuroendocrine tumor.	
FDG-PET/CT whole body	4	This procedure is not appropriate unless there is a known malignancy.	
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 6</u>: Indeterminate <1 cm lesion on initial imaging with ultrasound, CT (without or with contrast), or non-contrast-enhanced MRI. Known or suspected liver disease associated with a high risk of hepatocellular carcinoma (chronic hepatitis, cirrhosis, hemochromatosis, etc.)

Radiologic Procedure	Rating	Comments	RRL*
Lesion Initially Identified on US			
MRI abdomen without and with contrast	9	Although MRI is the best test for characterizing liver lesions, it may have limitations for characterizing small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	О
MRI abdomen without contrast	6	Consider this procedure if MRI with gadolinium is contraindicated. However, this may not be the case for small lesions.	О
Rating Graden Walab Wandywich copprag	ogriate; 74,5,6 May be appropriate;	7.8. Or Side of the lesion is not cystic on US and MRI is not available or contraindicated.	*Relative Radiation Level

Radiologic Procedure contrast	Rating	Comments Consider this procedure if there is a contraindication to MRI and CT contrast agents.	RRL*
CT abdomen with contrast	6	Consider this procedure if the lesion is not cystic on US and MRI is not available or contraindicated.	
Lesion Initially Identified on CT			
MRI abdomen without and with contrast	9	Consider this procedure if characterization by CT is incomplete, recognizing the limitations of MRI for characterizing small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	O
MRI abdomen without contrast	6	Consider this procedure if MRI with gadolinium is contraindicated.	О
US abdomen	5	Consider this procedure to differentiate between a cystic versus solid lesion or to guide a biopsy/intervention.	O
Lesion Initially Identified on MRI Without	Contrast		
MRI abdomen without and with contrast	9	Consider this procedure to differentiate between benign and malignant lesion. However, there may be challenges when attempting to characterize small lesions. See statement regarding contrast in the text below under "Anticipated Exceptions."	O
CT abdomen without and with contrast	7	Consider this procedure if MRI with gadolinium is contraindicated and knowledge of the enhancement pattern will help with the differential diagnosis.	
CT abdomen without contrast	3	Consider this procedure if there is a contraindication to CT and MRI contrast agents.	
CT abdomen with contrast	6	Consider this procedure if there is a contraindication to MRI contrast agents.	
US abdomen	5	This procedure is usually not indicated after MRI.	O
Lesion Initially Identified on US, CT, or M	ИRI		
Percutaneous image-guided biopsy liver	6	Consider this procedure if imaging findings are atypical, inconclusive, or suspicious for malignancy after performing a CT or MRI with contrast. However, there may be challenges when attempting to biopsy small lesions.	Varies
Tc-99m sulfur colloid scan liver	3	Consider this procedure to evaluate for FNH if GFR precludes CT or MRI with contrast.	
Rating Sank Cls 22 h liverally not appropria	te;34,5,6 May be appropriate;	7.8.0.4. Assistantly suppropriate if a hemangioma is suspected	*Relative

Radiologic Procedure	Rating	and if GFR precludes CT or MRI with contrast.	RRL*
In-111 somatostatin receptor scintigraphy	3	This procedure is not appropriate unless there is a known or suspected neuroendocrine tumor.	
FDG-PET/CT whole body	3	This procedure is not appropriate unless there is a known malignancy.	
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

Summary of Literature Review

Introduction/Background

Due to the high prevalence of benign focal hepatic lesions in adults, liver lesion characterization is an important objective of diagnostic imaging. Incidental liver masses are often discovered in healthy adults during routine imaging procedures as well as during staging of a known malignancy, and they need to be characterized.

Common benign liver masses include cysts, biliary hamartomas, and hemangiomas; common malignant tumors include metastases and hepatocellular carcinomas (HCCs). Less common liver tumors include focal nodular hyperplasia (FNH), hepatocellular adenoma, fibrolamellar HCC, intrahepatic cholangiocarcinoma, biliary cystadenoma and cystadenocarcinoma, lymphoma, stromal tumors, a variety of sarcomas, hemangioendothelioma, and hepatoblastoma, the latter occurring in children. On occasion, nontumorous masses may mimic liver tumors. These mimics include focal fat deposition or sparing, abscess, hematoma, vascular shunts such as the ones to treat portal venous-hepatic venous malformations, peliosis hepatis and transient hepatic attenuation differences on computed tomography (CT), or transient hepatic intensity differences on magnetic resonance imaging (MRI). Patients with cirrhosis are a special group in whom certain benign (regenerating nodules), premalignant (dysplastic nodules), malignant (HCC), and nontumorous (confluent hepatic fibrosis) masses are more prevalent.

For each of the variants in this document, it is assumed that some prior imaging study has been performed and identified a lesion that may or may not be characterized by the initial imaging evaluation, or it is assumed that the initial technique was suboptimal from a technical standpoint. Prior imaging studies may include ultrasonography (US) with color-flow evaluation, noncontrast and/or contrast-enhanced multidetector helical CT, or noncontrast and/or contrast-enhanced MRI.

This topic has been addressed somewhat differently in the White Paper of the American College of Radiology (ACR) Incidental Findings Committee. That document attempted to address what to do with an incidental liver lesion detected on CT only. Masses were divided into 3 size categories (<0.5 cm, 0.5 cm–1.5 cm, and >1.5 cm) and then stratified based on size, risk factors, and/or CT imaging characteristics into benign or suspicious. This American College of Radiology (ACR) Appropriateness Criteria® (AC) document addresses if and how to characterize a hepatic mass detected with any modality.

For purposes of increased clarity, in this AC, the panel members combined the low-risk and average-risk individuals into one category using the definitions as stated in the White Paper (any age with no known malignancies, hepatic dysfunction, hepatic cancer risk factors, or symptoms attributable to the liver). The definition of a high-risk individual in this AC differs from the White Paper in that the guideline authors separate those individuals with pre-existing liver disease (cirrhosis, hepatitis, chronic active hepatitis, sclerosing cholangitis, primary biliary cirrhosis, hemochromatosis, hemosiderosis, and hepatic dysfunction) from those with a known primary malignancy. Lastly, the guideline authors use a size cutoff≤1 cm as there are no data to support a different approach for patients with lesions <5 mm and 5 to 10 mm. In this revision, the authors added 3 more clinical variants for indeterminate masses <1 cm in size: <1 cm lesion, low-risk, and average-risk individual; <1 cm, high-risk individual, suspected metastatic disease, known extrahepatic malignancy (EHM); <1 cm, high-risk individual with underlying liver disease.

"Liver lesion characterization" is undertaken for hepatic masses seen by US, CT, or MRI. For the variant analysis, one can consider the following combination of: I) lesion characteristics and II) clinical risk factors:

I. Lesion characteristics (size and appearance)

- Larger than 1 cm
 - *Typical benign*: Liver lesion where the US, CT, or MRI appearance is diagnostic or highly suggestive of a benign mass (cyst, hemangioma, focal fat, or FNH). This may occur in a patient with or without a known history of malignancy.
 - *Typical malignant*: Liver lesion with a US, CT, or MRI appearance that is highly suggestive of a malignant mass (HCC, cholangiocarcinoma, or metastases) in a patient who may or may not have a known malignancy.
 - *Indeterminate (variants 1-3)*: Liver lesion with a US, CT, or MRI appearance that is indeterminate. This may occur in a patient with a background of normal liver, chronic liver disease, or known extrahepatic primary malignancy.
- Smaller than 1 cm indeterminate: Liver lesions <1 cm with a US, CT, or MRI appearance is indeterminate, regardless of clinical history.

II. Clinical risk factors

- History of extrahepatic malignancy (EHM)
- Underlying history of liver disease (e.g., cirrhosis, hepatitis B or C, primary sclerosing cholangitis, steatohepatitis)

Diagnostic Tests

To characterize a liver lesion discovered by US, CT, or MRI, the following diagnostic studies may be considered:

- Dynamic contrast-enhanced CT (multidetector helical)
- MRI (including contrast enhancement with gadolinium chelates)
- Sonography: Routine gray scale and Doppler US
- CT/positron emission tomography (PET) with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG)
- Nuclear scintigraphy (technetium-99 metastable [Tc-99m] sulfur colloid or Tc-99m red blood cell [RBC], OctreoScan)
- · Percutaneous image-guided biopsy

When considering possible studies for liver lesion characterization, it is assumed that a logical sequence will be followed. For example, if MRI and biopsy are considered appropriate tests, it is assumed that the biopsy will be done if the MRI is nondiagnostic. In this case, both studies should be considered "indicated."

Special Considerations

- Lesions previously characterized as benign: For a lesion previously characterized as benign, follow-up imaging is not usually indicated unless the patient has new symptoms or a change in the size, attenuation, signal intensity, or degree/pattern of enhancement of a benign lesion, which is a cause for concern.
- *Indeterminate lesions*: For indeterminate liver lesions >1 cm in all other categories described above, a biopsy should be considered when the findings from the additional imaging tests are inconclusive. Alternatively, in certain clinical situations, short-term imaging surveillance (3 to 4 months) can be useful to monitor lesion stability. Depending on the stability of the lesion or the underlying disease process, interval scans may be extended over longer periods (e.g., 6 to 12 months) and repeated as necessary, especially in the setting of underlying liver disease.
- Subcentimeter lesion: These lesions are difficult to characterize, although MRI may be helpful. In patients with extrahepatic primary malignancy, these small lesions are often evaluated with follow-up imaging since most are benign.

Contrast Agents

Ultrasound Contrast Agents

Research performed outside the United States on second-generation US contrast agents has demonstrated high accuracy in characterizing liver lesions. These agents consist of either stable perfluorocarbon nanoparticles or sulfur hexafluoride microbubbles; they are injected intravenously and insonated with low acoustic pressure. The nanoparticles emit a harmonic signal and can be detected with pulse inversion recovery to demonstrate the vascular architecture of a lesion, as well as the temporal course of enhancement, thereby allowing characterization of the lesion. These agents have not been approved for hepatic imaging in the United States.

MRI Contrast Agents

MRI contrast agents, such as mangafodipir and ferumoxides may be of value for distinguishing between benign and malignant primary hepatocellular tumors and for detecting metastatic disease. However, experience with the use of these agents is mainly limited to phase III clinical

trials, and these agents are not widely available for clinical use. At this time, mangafodipir is not available for clinical use in the United States.

Gadobenate dimeglumine can be used to differentiate FNH from other lesions such as hepatocellular adenoma. Approximately 5% of this agent is metabolized by the liver, accumulating in the biliary ductule cells present in FNH and resulting in mild persistent enhancement on delayed imaging at 1 to 3 hours after contrast administration. Newer liver-specific agents such as gadoxetic acid have approximately 50% hepatic uptake and metabolism, accumulating in healthy liver cells and resulting in persistent enhancement of the background liver and no enhancement of lesions that do not contain functioning hepatocytes. With this agent, there is mild to vivid enhancement of FNH on delayed imaging at 10 to 20 minutes after contrast administration. FNH is not known to occur in the cirrhotic liver. Therefore, delayed uptake in such cases should not favor a benign process since well-differentiated HCC may have functioning hepatocytes. These newer agents enable a delayed hepatobiliary phase in addition to hepatic arterial, portal venous, and equilibrium phase MR imaging for lesion detection and characterization and detection.

Recommendations (see also Appendices 1 and 2 in the original guideline document)

- Typical benign mass: no history of malignancy. Liver masses with typical imaging features of simple cyst, hemangioma, hepatic adenoma, or FNH in patients who are not known to have, or are not suspected of having, a malignancy may be classified as benign. Focal fat deposition or focal sparing in a liver with otherwise diffuse fat deposition can generally be diagnosed when typical features are seen on sonography, noncontrast CT, and, most reliably, MRI using chemical shift (in phase and out of phase) imaging. These typical benign lesions do not require further follow-up if they have been characterized as a benign process.
- Typical benign mass: known history of malignancy. Liver masses with typical imaging features of simple cyst, hemangioma, or FNH in patients who are known to have a malignancy may be considered benign and do not require follow-up. However, if there is any doubt that the mass is benign, tumor markers, short-interval follow-up, imaging or biopsy should be considered.
- Typical malignant mass: Lesions with typical imaging features of a malignant mass do not require additional imaging, but confirmation with serum tumor markers (e.g., alpha fetoprotein in the case of HCC) or percutaneous biopsy image-guided may be appropriate. In some cases, additional imaging such as nuclear scintigraphy (somatostatin receptor) or PET/CT can be performed to fully stage the extent of disease prior to an invasive biopsy, particularly if there is a history of primary EHM.
- Indeterminate mass > 1 cm: low-risk or average-risk individual (variant 1). For indeterminate masses on background of normal liver, additional imaging may be required for tissue characterization.

 If the initial indeterminate imaging test is US or CT, then MRI should be considered for liver lesion characterization. MRI would be particularly preferred in pediatric and young adult patients due to its lack of ionizing radiation. Nuclear scintigraphy is an option in patients with suspected FNH (using technetium-labeled sulfur colloid). US can have a role in cases of T2 hyperintense lesions found on MRI and hypodense lesions found on CT to determine whether they are solid or cystic or to confirm a hemangioma.
- Indeterminate mass >1 cm: high-risk individual, suspect metastatic disease, known EHM (variant 2). In these patients, interval follow-up imaging is usually not a practical option due to the need to initiate appropriate treatment. Dynamic contrast-enhanced, multiphase, multidetector CT, multiphase MRI (with a gadolinium chelate), or contrast-enhanced US (only available outside the United States) may be used to characterize a lesion further and identify additional lesions in the setting of metastatic disease. Percutaneous image-guided liver biopsy should always be considered and will enable tissue diagnosis.

 If the underlying extrahepatic primary malignancy is FDG avid (e.g., melanoma, colon and esophageal cancer, breast cancer, sarcoma) and the diagnosis of liver metastasis will influence patient management, PET/CT imaging may be useful. Note, however, that metastases from mucin-producing colorectal carcinoma may not be FDG avid. Furthermore, HCC may not be FDG avid. Nuclear scintigraphy is also an option for further staging in patients with an underlying primary neuroendocrine malignancy (somatostatin receptor scintigraphy).
- Indeterminate mass > 1 cm: high-risk individual with underlying liver disease (variant 3). Characterization of liver lesions in a cirrhotic liver may be performed with either multiphase MRI (with a gadolinium-chelate) or dynamic contrast-enhanced multiphase, multidetector CT. Characterization is more definitive for lesions >2 cm in diameter. MRI may be useful to characterize indeterminate masses identified on CT or US. If the mass remains indeterminate after MRI, then percutaneous image-guided biopsy may be needed to make a final diagnosis. Percutaneous biopsy may not be indicated in patients who are liver transplant candidates due to the risk of needle-tract seeding. In such cases, short-term follow-up imaging in 3 to 6 months may be obtained. Digital subtraction angiography may also be obtained in these patients, and if a tumor stain is detected, chemoembolization is performed as a bridge to transplantation.
- Subcentimeter lesion. Subcentimeter lesions can be benign or malignant, although the majority are benign, even in a patient with a known EHM. Benign lesions are usually a result of hepatobiliary fibrocystic continuum such as biliary hamartomas, microhamartomas, and simple cysts. Small hepatic cysts can also be seen in patients who have experienced a prior insult such as a biopsy of or trauma to the liver. These subcentimeter lesions are nonspecific on US and CT partly due to their small size and volume averaging. MRI may help confirm their cystic nature and benignity, especially in a patient with underlying malignancy or chronic liver disease. When a subcentimeter lesion is poorly detected or indeterminate on MRI and there is either underlying liver disease or EHM, where there is greater risk of a malignant lesion, initial short-term surveillance (3 months) can be useful to monitor lesion stability. Depending on the stability of the lesion or underlying disease

process, interval scans can be extended over longer periods, e.g., 6 months to 1 year. In the case of extrahepatic malignancy, contrast-enhanced CT is most efficacious for whole-body staging unless the patient's glomerular filtration rate (GFR) precludes an enhanced examination. For patients with underlying liver disease, MRI may be more helpful for further characterization, specifically in delineating regenerative, siderotic, or dysplastic nodule as well as HCC.

- Three additional variants have been created to deal with small indeterminate lesions:
 - Indeterminate <1 cm mass in a low-risk or average-risk individual (variant 4): In almost all low-risk or average-risk individuals, an indeterminate <1 cm liver lesion is benign. If indeterminate on US or CT, MRI may characterize the lesion. However, unless there is patient anxiety, one could argue that no further characterization of these lesions is indicated. The best course may be to perform no further imaging. If patient anxiety is high, a follow-up in 3 to 4 months, preferably with MRI, may allay their fears.
 - Indeterminate <1 cm lesion in a high-risk individual, with suspect metastatic disease, known EHM (variant 5): If a <1 cm lesion is detected with US or CT and cannot be fully characterized, MR may characterize the lesion as a cyst, hemangioma, hamartoma, or focal fat. If MR does not characterize the lesion, short-term follow-up (3 to 6 months) is recommended.
 - Indeterminate <1 cm mass in a high-risk individual with underlying liver disease (variant 6): If an indeterminate <1 cm lesion is detected with US in a patient with underlying liver disease, the differential diagnosis includes hyperplastic nodule, dysplastic nodule, or small HCC. Even though most of these lesions cannot be further characterized, given their size it is reasonable to obtain a multiphasic, enhanced CT or precontrast and postcontrast-enhanced MRI, with MRI preferred to CT. Likewise, if an indeterminate <1 cm lesion is detected on a multiphasic, enhanced CT it is not unreasonable to seek further characterization with precontrast and postcontrast-enhanced MRI in 3 months.

Summary

- MRI without and with contrast is the technique of choice for the characterization of indeterminate focal liver lesions. This includes lesions of all sizes, even those <1 cm. It also includes patients without or with either EHM or chronic liver disease. When either an MRI with contrast or a CT with contrast is contraindicated in patients with renal insufficiency, especially when the estimated GFR (eGFR) is <30 mL/min, an MRI without contrast is the technique of choice.
- CT with contrast is the technique of choice for the characterization of indeterminate focal liver lesions in patients who cannot undergo an MRI with contrast, including lesions of all sizes and in patients without or with an EHM or chronic liver disease. When a survey examination of the entire abdomen and pelvis or the chest, abdomen, and pelvis is needed for the evaluation of patients with an EHM, a CT with contrast is preferred to an MRI. For most indications, a CT with contrast is preferred to an MRI without contrast. A CT without contrast, however, has a very limited role in the characterization of indeterminate focal liver lesions.
- US has a limited role in the characterization of indeterminate focal liver lesions, although it can be useful for differentiating solid from cystic lesions. It is very useful for guiding the percutaneous biopsy of a focal liver lesion, assuming, of course, that the lesion is visible with US.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the ACR Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- CT, computed tomography
- FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography
- FNH, focal nodular hyperplasia
- GFR, glomerular filtration rate
- HCC, hepatocellular carcinoma
- In-111, Indium-111
- MRI, magnetic resonance imaging
- RBC, red blood cell
- Tc-99m, technetium-99 metastable
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
0	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv

^{*}RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

Clinical Algorithm(s)

The following algorithms are provided in the appendices in the original guideline document:

- Indeterminate mass > 1 cm on initial imaging
- Indeterminate mass < 1 cm on initial imaging

Scope

Disease/Condition(s)

Liver lesion

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Gastroenterology

Internal Medicine

Nuclear Medicine

Oncology

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for initial liver lesion characterization

Target Population

Patients with a liver lesion

Interventions and Practices Considered

- 1. Ultrasound (US) abdomen
- 2. Computed tomography (CT) abdomen
 - Without and with contrast
 - Without contrast
 - With contrast
- 3. Magnetic resonance imaging (MRI) abdomen
 - Without and with contrast
 - Without contrast
- 4. Technetium-99 metastable (Tc-99m) liver scan
 - Sulfur colloid
 - Red blood cell (RBC)
- 5. Indium-111 (In-111) somatostatin receptor scintigraphy
- 6. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET)/CT whole body
- 7. Percutaneous image-guided liver biopsy

Major Outcomes Considered

- Utility of radiologic examinations in differential diagnosis
- Sensitivity, specificity, accuracy, and positive and negative predictive value of radiologic examinations

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

- 1. Articles that have abstracts available and are concerned with humans.
- 2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
- 3. May restrict the search to Adults only or Pediatrics only.
- 4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Study Quality Category Definitions

- Category 1 The study is well-designed and accounts for common biases.
- Category 2 The study is moderately well-designed and accounts for most common biases.
- Category 3 There are important study design limitations.

Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:

- a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description).
- b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence.
- c. The study is an expert opinion or consensus document.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an

appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for initial liver lesion characterization

Potential Harms

Gadolinium-Based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Contraindications

Contraindications

Contrast agents are contraindicated in patients with renal insufficiency, especially when the estimated glomerular filtration rate is less than 30 ml/min.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Nelson RC, Kamel IR, Baker ME, Al-Refaie WB, Cash BD, Harrison SA, Hindman NM, Kaur H, McNamara MM, Qayyum A, Tulchinsky M, Yarmish GM, Rosen MP, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® liver lesion -- initial characterization [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 24 p. [81 references]

Adaptation



	copies: Available from the ACR Web site
•	ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013
	Nov. 3 p. Electronic copies: Available from the ACR Web site
•	ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2013 Nov. 3 p.
	Electronic copies: Available from the ACR Web site
•	ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies:
	Available from the ACR Web site
•	ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies:
	Available from the ACR Web site
•	ACR Appropriateness Criteria® liver lesion — initial characterization. Evidence table. Reston (VA): American College of Radiology; 2014.
	27 p. Electronic copies: Available from the ACR Web site

Patient Resources

None available

NGC Status

This summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This summary was updated by ECRI on March 31, 2003. The updated information was verified by the guideline developer on April 21, 2003. This summary was updated by ECRI on August 11, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 27, 2011 and July 16, 2014.

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